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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,724	12/06/2005	Yoshiaki Suzuki	P26894	8295
7055 7590 01/22/2008 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER ZACHARIA, RAMSEY E	
			ART UNIT 1794	PAPER NUMBER
			NOTIFICATION DATE 01/22/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

## Office Action Summary

Application No.

10/525,724

Applicant(s)

SUZUKI ET AL.

Examiner

Ramsey Zacharia

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 02/24/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Information Disclosure Statement*

1. The fourth and fifth references under the "Other Documents" section of the IDS filed 24 February 2006 have been lined through because no references that could be identified by the titles "Ion Bean Ni Yoru ePTFE Jinko Komaku No Kaistitsu -Sohiki Oyobi Fibrin Nori Saibo Secchakusei No Fuyo-" or "Ion Beam Shosha Ni Yoru ePTFE Jinko Komamku No Kairyo" could be found in the application nor were any concise explanations of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of these references.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Izukawa et al. (J. Vac. Soc. Jpn. Vol 45, No 6., pp 514-518).

Izukawa et al. teach a polylactic acid having a surface that has been modified by carbon ion implantation. The implantation was performed at a dose of  $1 \times 10^{14}$  to  $1 \times 10^{16}$  ions/cm<sup>2</sup>. See abstract.

Regarding limitations that the polymeric material is used in combination with a tissue adhesive and used for an artificial dura mater, blood vessel, patch or suture, these represent intended uses of the polymeric material. These limitations are met since it has been held that a recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Likewise, the limitations of claim 2 are also met since this claim merely further limits the tissue adhesive with which the claimed polymeric material is intended to be used.

4. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (Ionics, Vol 27, No. 7, pp 3-11).

Suzuki et al. teach ePTFE for use as artificial dura mater having a surface that has been modified by ion beam irradiation. In the embodiments of the examples, the irradiation was performed at doses of  $1 \times 10^{14}$ ,  $5 \times 10^{14}$ , and  $1 \times 10^{15}$  ions/cm<sup>2</sup>.

Regarding the limitation that the polymeric material is used in combination with a tissue adhesive, this represent an intended use of the polymeric material. This limitation is met since it has been held that a recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Likewise, the limitations of claim 2 are also met since this claim merely further limits the tissue adhesive with which the claimed polymeric material is intended to be used.

5. Claims 1, 2, and 4-7 rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (US 5,152,783).

Suzuki et al. teach an artificial biocompatible material that may be used as an artificial blood vessel (column 1, lines 5-9). Silicone, a polymeric material which comprises silicon as a constitutional element, is the most preferred artificial material (column 2, lines 24-29). The amount of ions implanted are usually in the range of about  $1 \times 10^{12}$  to  $3 \times 10^{17}$  ions/cm<sup>2</sup> (column 2, lines 34-39).

Regarding the limitation that the polymeric material is used in combination with a tissue adhesive, this represent an intended use of the polymeric material. This limitation is met since it has been held that a recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Likewise, the limitations of claim 2 are also met since this claim merely further limits the tissue adhesive with which the claimed polymeric material is intended to be used.

6. Claims 1-7 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Suzuki et al. (US 2002/0155295).

Suzuki et al. is directed to a material that may be used as an artificial dura mater (paragraph 0001). The material is subjected to ion implantation (paragraph 0005). The material

may be ePTFE, polylactic acid, or polyglactin (paragraph 0039). The dose is preferably  $1 \times 10^{15}$  to  $1 \times 10^{16}$  ions/cm<sup>2</sup> (paragraph 0041).

Regarding the limitation that the polymeric material is used in combination with a tissue adhesive, this represent an intended use of the polymeric material. This limitation is met since it has been held that a recitation with respect to the manner in which a claimed product is intended to be employed does not differentiate the claimed product from a prior art product satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Likewise, the limitations of claim 2 are also met since this claim merely further limits the tissue adhesive with which the claimed polymeric material is intended to be used.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 2, and 4-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 5,308,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of instant claims 1, 2, and 4-7 represent a genus (since they are directed to polymeric materials which comprise either carbon or silicon as constitutional elements) of which the inventions described by claims 1 and 5 of U.S. Patent No. 5,308,704 are species. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). See the discussion above regarding the intended use limitations in instant claims 1, 2, and 4-7.

9. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,872,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of instant claims 1-7 represent a genus (since they are directed to polymeric materials which comprise either carbon or silicon as constitutional elements) of which the inventions described by claims 1-7 of U.S. Patent No. 6,872,759 are species. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). See the discussion above regarding the intended use limitations in instant claims 1-7.

10. Claims 1, 2, and 4-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 5,152,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of instant claims 1-7 represent a genus (since they are directed to polymeric


materials which comprise either carbon or silicon as constitutional elements and which may be modified by any ions) of which the inventions described by claims 1 and 15 of U.S. Patent No. 5,152,783 are species. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). See the discussion above regarding the intended use limitations in instant claims 1, 2, and 4-7.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramsey Zacharia whose telephone number is (571) 272-1518. The examiner can normally be reached on Monday through Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached at (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Ramsey Zacharia**  
**Primary Examiner**  
**Tech Center 1700**